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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/480,236	01/10/2000	Mary Ellen Digan	4-31157A/USN	4092

1095 7590 02/24/2003

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

24

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.

09/480,236

Applicant(s)

Digan et al.

Examiner

G.R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Feb 3, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE:

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attachment
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: none
- Claim(s) objected to: none
- Claim(s) rejected: 35-54
- Claim(s) withdrawn from consideration: \_\_\_\_\_
8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's Remarks, filed 2/03/03, are acknowledged.
2. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
3. Claims 51-53 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record as set forth in the rejections of Claims 31-33 in Papers No. 9.

Applicant's arguments, filed 2/03/03, have been fully considered but are not found persuasive. Applicant argues that, the ruling as set forth in *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609 (Fed. Cir., 2002) is "controlling for the present situation." It is the Examiner's position that the facts of *Enzo* are unrelated to the instant rejections. As indicated in Applicant's arguments, the *Enzo* claims recited sequences that hybridized under stringent conditions. No such limitations are recited in the instant claims. It appears that Applicant's argument is that stringent hybridization is analogous to 90% identity, a position for which Applicant provides no actual argument or support. Accordingly, the rejection is maintained.

4. Claims 50-51 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for,  
a recombinant immunotoxin polypeptide consisting of the polypeptide encoded by the nucleotide sequence of SEQ ID NO:2, does not reasonably provide enablement for:  
a recombinant immunotoxin polypeptide comprising an antibody having a variable region which is at least about 90% identical to the variable region of UCHT-1 and is at least about 90% as effective as UCHT-1 for binding human CD3, for the reasons of record as set forth in the rejections of Claims 31-33 in Paper No. 17, mailed 3/28/02.

Applicant's arguments, filed 2/03/03, have been fully considered but are not found persuasive. Applicant argues that the functional description of the claims is sufficient enablement. It remains the Examiner's position that the functional limitations of the claims remain insufficient as the limitations continue to comprise only a trial-and-error sort of enablement, i.e., if an antibody comprises the limitations, then it is encompassed by the claims. It remains the Examiner's position that this limited guidance cannot be considered to be enabling.

5. Claim 50 stands rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed for the reasons of record as set forth in Paper No. 22, mailed 11/21/02. This is a new matter rejection.

Applicant's arguments, filed 2/03/03, have been fully considered but are not found persuasive. Applicant argues that the disclosure at page 38 of the specification of "... as well as complementary strands of the foregoing nucleic acids," and "which hybridizes to a polynucleotide which encodes a polypeptide of the invention," is sufficient written description for the polypeptide of the claim. It remains the Examiner's position that the generic disclosure at page 38 cannot support the specific limitation, i.e., at least 300 complementary bases of SEQ ID NO:2, recited in the claim.

6. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 35-54 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,103,235 (2000, of record) in view of Kreitman et al. (1995, of record) and Kreitman et al. (1994, of record), for the reasons of record as set forth in the rejections of Claims 1-7, 9-16, 29-30, and 33-34, in Paper No. 17, mailed 3/28/02.

Applicant's arguments, filed 2/03/03, have been fully considered but are not found persuasive. Applicant appears to be arguing that the rejection is based on the presumption of "obvious to try", which Applicant argues is in error. The rejection is actually based on the obviousness of employing interchangeable parts, i.e., PE toxins for DT toxins, as taught by the Kreitman et al. references.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600  
February 23, 2003